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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,178	07/15/2003	Karel De Bruijn	4-30602B-D1	8650

1095 7590 09/23/2005

NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

EXAMINER
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DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No. 10/620,178		Applicant(s) DE BRUIJN ET AL.	
Examiner Cybille Delacroix-Muirheid		Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 46, 47 and 52 is/are allowed.
- 6) ☒ Claim(s) 27-45 and 48-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>05/02/05</u> . | 6) <input type="checkbox"/> Other: _____  |

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***Detailed Action***

The following is responsive to applicant's amendment received June 28, 2005.

Claims 1-26 are cancelled. No new claims are added. Claims 27-52 are currently pending.

The previous objection of claims 36, 39 and 42 set forth in the office action mailed Dec. 28, 2004 is withdrawn in view of applicant's amendment and the remarks contained therein.

However, prosecution on the merits is reopened in view of the following new ground(s) of rejection based upon a newly discovered reference.

The indication of allowable subject matter of claims 27-35, 37-38, 40-41, 43-45, 48-51 is withdrawn in view of the following new ground(s) of rejection.

***Claim Rejection(s)—35 USC 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 27-45, 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/22340 ('340) in view of Giger et al., 5,510,353.

WO '340 discloses a tablet composition comprising tolfenamic acid (hydrophobic compound), alginic acid and at least 6% by weight of a superdisintegrant. Specifically, the superdisintegrants may include crospovidone, sodium starch glycolate and carboxymethylcellulose. WO '340 teach that the superdisintegrant may be present in an amount at least 8%, 10% or 12% by weight. Although there is no particular upper limit, from a cost point of view the amount of superdisintegrant will preferably not exceed 15-20% by weight as normally no particular benefits will be achieved beyond this range. Finally, WO '340 discloses that the remainder of the composition may contain other conventional tablet formulation aids such as fillers, binding agents, disintegrant, lubricants, etc. Please see page 3, line 7 to page 4, line 3; page 5, lines 32-34; page 7, lines 1-3.

WO '340 does not disclose a tablet composition containing an acid sensitive agent such as the claimed serotonergic compound. However, the examiner refers to Giger et al., which disclose pharmaceutical compositions containing as the active agent the compound (3-(5-methoxy-1H-indol-3-yl-methylene)-N-pentylcarbazimidamide or salts thereof and

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pharmaceutically acceptable carriers. Please see col. 1, lines 15-18; Example 13, Table 1; col. 21, lines 25-30.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tablet compositions of WO '340 to contain the serotonergic compound (3-(5-methoxy-1H-indol-3-yl-methylene)-N-pentylcarbazimidamide or salts thereof because WO '340 discloses that the tablet composition is capable of rapid release of the active ingredient (page 1, lines 5-8; page 2, lines 32-35) and one of ordinary skill in the art would reasonably expect the resulting tablet composition to rapidly release (3-(5-methoxy-1H-indol-3-yl-methylene)-N-pentylcarbazimidamide or salts thereof thereby decreasing the amount of time required to render a therapeutic effect.

Concerning, claims drawn to specific surfactants and lubricants, since WO '340 teach that lubricants, surfactants are conventional carriers used in formulating tablets, it would have been obvious to one of ordinary skill in the art to further modify the compositions of WO '340 such that the tablet composition contains excipients suitable for therapeutic use.

#### ***Allowable Subject Matter***

Claims 46-47, 52 are free from the prior art because the prior art does not disclose or fairly suggest the claimed pharmaceutical composition.

#### ***Conclusion***

Claims 27-45, 48-51 are rejected.

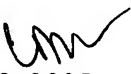
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybillie Delacroix-Muirheid** whose telephone number is **571-**

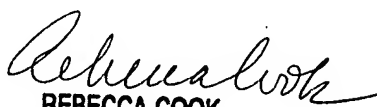
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**272-0572.** The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM   
Sep. 19, 2005

  
REBECCA COOK  
PRIMARY EXAMINER  
GROUP 4200 1614